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CMDh/305/2013
March 2018, Rev.02

Summary Public Assessment Report

Generics

Casaro HCT
Candesartan cilexetil/hydrochlorothiazide

SK/H/0267/001-002/DC

Date: May 2022

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Casaro HCT

Candesartan cilexetil/hydrochlorothiazide, tablets, 16 mg/12.5 mg and 32 mg/12.5 mg

This is a summary of the public assessment report (PAR) for Casaro HCT. It explains how Casaro HCT was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Casaro HCT.

For practical information about using Casaro HCT patients should read the package leaflet or contact their doctor or pharmacist.

What is Casaro HCT and what is it used for?

Casaro HCT is a 'generic medicine'. This means that Casaro HCT is similar to a 'reference medicine' already authorised in the European Union (EU) called Atacand Plus.

Casaro HCT is used in the treatment of high blood pressure (hypertension) in adult patients.

How does Casaro HCT work?

Casaro HCT contains two active ingredients: candesartan cilexetil and hydrochlorothiazide. These work together to lower your blood pressure.

- Candesartan cilexetil belongs to a group of medicines called angiotensin II receptor antagonists. It makes your blood vessels relax and widen. This helps to lower your blood pressure.

- Hydrochlorothiazide belongs to a group of medicines called diuretics (water tablets). It helps your body to get rid of water and salts like sodium in your urine. This helps to lower your blood pressure.

How is Casaro HCT used?

The pharmaceutical form of Casaro HCT is tablet and the route of administration is oral.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Casaro HCT have been shown in studies?

Because Casaro HCT is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Atacand Plus. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Casaro HCT?

Because Casaro HCT is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of restrictions, see the package leaflet.

Why is Casaro HCT approved?

It was concluded that, in accordance with EU requirements, Casaro HCT has been shown to have comparable quality and to be bioequivalent to Atacand Plus. Therefore, the State Institute for Drug Control decided that, as for Atacand Plus the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Casaro HCT?

A risk management plan has been developed to ensure that Casaro HCT is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Casaro HCT, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Casaro HCT

The marketing authorisation for Casaro HCT was granted on 13 July 2022.

The full PAR Casaro HCT can be found on the website https://www.sukl.sk/. For more information about treatment with Casaro HCT, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in 05/2022.